TECHNOLOGY TRANSFER COMMUNITY NEWSLETTER

May 2018

ETT System — Update

ETT Project Approaches Critical Milestone

David Vismer, Sapient

For the past several months, the Enterprise Technology Transfer System (ETT) Project Team has been working with several different working groups, made up of representatives covering the full breadth of the NIH technology transfer community, to document all the business processes, roles and responsibilities, and tools that are used by the community to advance NIH discoveries. The artifacts developed in these working group sessions will serve not only to define the needs of the ETT system, but also to guide the maintenance of the community's information systems over the long term.

After the working groups completed their analysis of the technology transfer business processes, the ETT Project Team began the definition of system features that would be necessary in the new ETT system, and the evaluation of systems currently in use within the community. The team used the evaluation of these existing systems to determine how the required system features are supported and to identify system features that are not currently supported.

As the project moves forward, the ETT Project Governance Group, along with the Office of Technology Transfer, will determine which systems best fit the needs of the community. Once system selection is completed, the project team can begin planning the implementation of the system and the migration of existing technology transfer data into it. The project is currently on track to begin the implementation later this year.

In preparation for the implementation of the new ETT system, the project team has begun working with focus groups, made up of experts in particular areas of the technology transfer business process, such as patenting & licensing, royalties, marketing, and monitoring & enforcement, to define the specific business requirements, and the related functional

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requirements, for the future ETT system. These requirements will allow the team to oversee the initial customization of the system and will provide a roadmap for the long-term maintenance and upgrade of the system throughout its lifecycle.

If you have any questions about the project, or would like to volunteer your time to share your expertise in our focus groups, please ask your supervisor to reach out to the ETT Project Governance Group for more information.

Service Desk Tickets

Sometimes, Tickets Are a Good Thing…

Tim Leahy, NIH-OTT

We asked and you listened—In FY2017, the Technology Transfer Community submitted over 380 Service Desk tickets related to issues with OTT SharePoint, NIH TechTracS, WARP and the LFP. This allowed the OTT to serve you more efficiently and to allow OTT management to more closely manage and measure our interactions with our customers. We are working on improving our response and resolution times, by triaging the tickets faster, and improving our relationships with our support contractors and CIT in order to more effectively perform root cause analysis on many complex issues.

Please continue to enter in service tickets (https://itservicedesk.nih.gov/support/) for questions and issues associated with:

- NIH TechTracS Data Entry
- NIH TechTracS How-Tos
- NIH TechTracS Report Generation
- NIH TechTracS Data Integrity
- CPI, AMS, or Annuities/Maintenance
- EIRs
- Records retention
- Patent/Patent family
- Status updates for EIRs, Patents, License Agreements, and Annuity payments

If you cannot access the NIH Helpdesk system, please contact Tim Leahy directly.

Ask Steve — Q&A

"Most of NIH inventions published on the OTT web site have been filed more than 5 years ago. Does it mean that these inventions are not attractive or industry doesn't consider them to have commercial prospects?"

The inventions listed on the OTT web site are the ones that haven't been licensed exclusively (exclusively licensed inventions are removed when requested by the IC) or are ones with some fields of use or research materials still available for licensing. Aging of unlicensed inventions is indeed a concern for NIH with the now post-GATT 20 year patent term from the priority filing date and the fact that US patent prosecution is largely deferred (via PCT / national phase filings). The situation is complicated by very early patent filings that start the patent clock that we need to do in order to file before the inventor publishes or otherwise discloses the invention. In terms of "aging" of unlicensed patent filings, the most definitive work on this topic that I've come across is the Bupp study from NCI (https://www.genomeweb.com/biotechtransferweek/nci-ip-licensing-study-shows-patent-age-influences-deal-probability) that found that 93 percent of all NCI licenses were executed within eight years of the patent priority date.

With tech transfer decentralization at NIH, it is important to still send in invention abstracts for publication on the OTT web site as soon as possible for maximum marketing opportunities. Interest from prospective licensees (or lack thereof) is important feedback when making PCT or National Phase foreign filing decisions at the IC. And of course eight years from the invention priority date will be here sooner than you think!

My colleagues Ajoy Prabhu and Elaine Ray from the OTT Marketing Group are available to assist with invention marketing abstract drafting and logistics issues.

Have your own licensing question or a discussion topic for an upcoming Licensing Forum session? Just ask Steve!

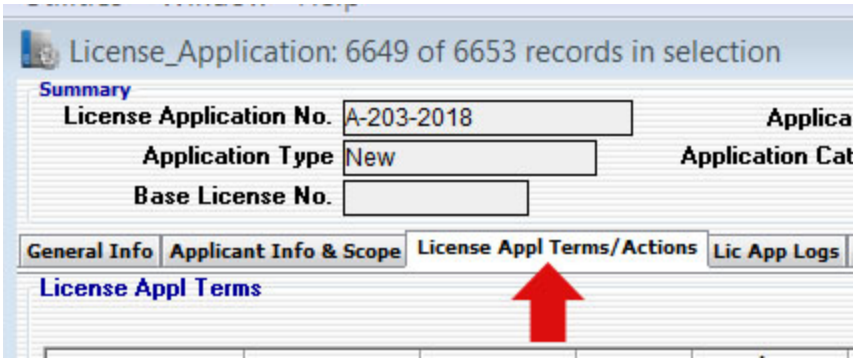
Steve Ferguson, NIH-OTT

TechTracS

Are Materials To Be Released?

Karen Rogers, NIH-OTT

The Royalties Administration staff in OTT want to let you know that the HHS Material Contact information field, located on the License Appl Terms/Actions tab should contain information for the NIH or CDC lab contact that will be shipping the materials to the licensee. We are noticing that this information is being left blank or contains the licensee shipping information. We would appreciate your help by providing the correct information when you forward your executed licenses to us in OTT.



Catalog of Philip S. Chen, Jr., Ph.D. Distinguished Lectures on Innovation and Technology Transfer

Ajoy Prabhu, NIH-OTT

OTT Website

For the past 13 years, NIH Deputy Director for Intramural Research and the NIH Office of Technology Transfer have invited guest speakers to talk at the Philip S. Chen, Jr., Ph.D. Distinguished Lecture on Innovation and Technology Transfer. The lectureship honors Dr. Chen's remarkable, diverse, and creative contributions to the NIH, especially to its Intramural Research Program and to the field of technology transfer. Over the years, NIH OTT has directed its website visitors to various websites within NIH to read about the guest speakers and view their presentations. NIH OTT has recently created a single webpage for visitors to view any of the previous lectures, including video-casts of their talk. The permalink for the list is available here: https://www.ott.nih.gov/reportsstats/philip-s-chen-jr-phd-distinguished-lecture-innovation-and-technology-transfer.

If you need any information on any past (or future) lectures, please email us at nihott@mail.nih.gov.

PDIS Project

Patent Data Integrity and Standardization Project

Jill Roering, NIH-OTT

Preparations are underway for readying the patent data currently in the NIH TechTracS database for migration to the new Enterprise Technology Transfer System (ETT). The goal of this effort is to examine the accuracy and completeness of the patent data and establish standards and formats for the bibliographic details in the patent records. These critical measures taken now are essential for a successful migration to the new system.

The patent data fields that are being examined during this effort are those fields containing bibliographic details: Application Date, Application Number, Publication Number, Publication Date, Patent Number and Issue Date. Title, Inventors, and Priority Filing data will also be used to cross-reference patent family details. It is with these data points that the data in NIH TechTracS is compared against those details published by country patent offices.

In addition to verifying the accuracy of the patent data fields, this phase includes data reconciliations in the following areas:

- Omitting oddities: Jack's Birthday "1948" date, fields with " * ", numeric fields with alpha characters, etc.
- Completing patent family details that may impact the term or status: PTAs, SPCs, old country laws vs. new, etc.
- Reviewing the calculation of patent term expiration dates

A tool was developed specifically for this project to partially automate the process of cross matching the data fields mentioned above for thousands of patents and patent applications across 155 countries. The approach and review are progressing on a country by country basis and the capability used for partial automation is tailored for each country. Australia, Canada, PCT, Europe and European validated European countries have been reviewed and the United States review has begun.

Once the partially automated process has reviewed all records in a country and the data conflicts are identified and weighted, we then follow behind the scripts and perform manual data reconciliations, also on a country by country basis. One will begin to see the evidence of the data integrity checks by the comments appearing in the Patent Logs tab. Australia and Canada are expected to be completed by the end of June.

Due to the complexities of patent law, there are some patent records that require further insight and guidance. When those scenarios occur or when substantive changes are needed, the TTM/TTMP/LPMs will be contacted prior to changes being made.

In addition to ensuring that the historical patent data is ready for the new ETT system, the lessons learned during this phase of the project will provide keener insight when developing new system requirements for patent data fields: standardization of number formats, role access, auto-calculating, etc.

Project progress updates will appear in future TT Community Newsletters.

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Patent Data Integrity and Standardization Project

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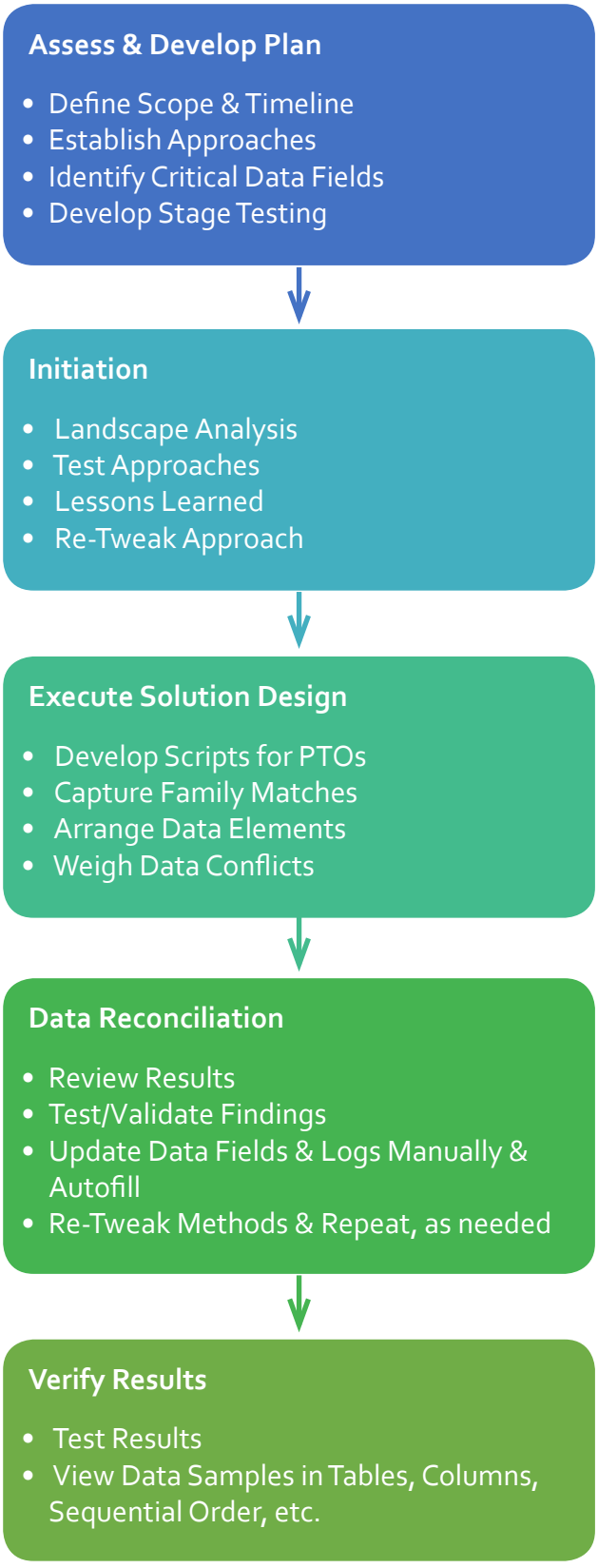

Updates from NCI TTC's Invention Development and Marketing Unit (IDMU)

Tom Stackhouse and Michael Salgaller, NCI

TTC's IDMU focuses on developing, facilitating, and executing strategies to increase licensing and partnership agreement activity for NCI and TTC's Client Institutes. Some notable achievements and activities include:

- **Outreach at BioPharm America 2017 Results in Signed Collaboration Agreement**

  Jinis Pharmaceutical, sought out by IDMU at BioPharm America 2017, has executed a collaboration agreement with NCI in February. The agreement will allow NCI's Dr. Bruce Shapiro to collaborate with Jinis to explore how their nanoparticles may provide the appropriate drug delivery system for his RNAi constructs. This resulting partnership is a great example of what TTC's IDMU is seeking to achieve through its outreach efforts.

- **International Outreach to Hong Kong**

  IMDU is working around the world and around the clock (sort of!) to find licensees and CRADA partners. Drs. Laura Prestia and Michael Salgaller were invited by the Hong Kong Economic and Trade Office to a March 2018 reception at the Smithsonian's Kogod Pavilion in celebration of the Chinese New Year. IDMU is working with the Hong Kong Science and Technology Park (HKSTP) to introduce TTC innovators and assets to HKSPT's >250 life science companies. Hong Kong investors who might fund start-ups based on TTC assets are part of the discussions – which could take place via webinar or trade mission to NIH.

Dr. Laura Prestia TTC/IDMU; Chinese New Year dragon - the dragon dance is often performed during Chinese New Year celebrations; Smithsonian's Kogod Pavilion, event meeting site

- **TTC Invention Development Program (IDP) Addresses Key Technical Hurdles Inhibiting Commercial Interest**

  For a third year, TTC's IDP continued to facilitate commercialization of NCI's Intramural Research Program (IRP) patent portfolio. The IDP accomplishes this by funding preclinical validation studies necessary to make an invention more commercially attractive and less risky for potential partners – a challenge for most early-stage inventions. Inventions selected for the FY2017 IDP included:

  1. "Angiogenesis-Based Cancer Therapeutic" (E-230-2011) - Don Bottaro, Ph.D., CCR, Urologic Oncology Branch

  2. "Small Molecule Inhibitors of Drug Resistant Forms of HIV-1 Integrase" (E-093-2013) - Terrence Burke, Jr., Ph.D., CCR Chemical Biology Laboratory and Stephen Hughes, Ph.D., CCR Retroviral Replication Laboratory

  3. "Non-invasive Diagnostic and Prognostic Assays for Early Stage Lung Cancer" (E-121-2013) - Curtis Harris, M.D., CCR Laboratory of Human Carcinogenesis

4. "High-mobility group N1 protein (HMGN1) is an immune enhancer" (E-069-2016) - Joost Oppenheim, M.D., CCR Cancer Inflammation Program

5. "Selective Treatment of Cancer Cells, HIV and Other RNA Viruses" (E-038-2012) - Bruce Shapiro, Ph.D., CCR RNA Biology Laboratory

6. "Synthetic Lipopeptide Inhibitors of RAS Oncoproteins" (E-293-2010) - Nadya Tarasova, Ph.D., CCR Cancer and Inflammation Program

The commercialization potential of these six technologies is enhanced by IDP-recommended projects that address key technical challenges limiting interest by companies. Notable developments include:

Four projects involve contracts for scale-up of proprietary NCI assets (small molecule, proteins, and nucleic acids) to provide the inventors with single, large batches of material for animal studies and shared projects with potential collaborators.

Two projects involve small molecules that are highly insoluble., These patented molecules will undergo solubility testing in panels containing different vehicles.

Solubility studies for Dr. Nadya Tarasova's therapeutic proscribed an injectable treatment strategy, and her small molecule Ras inhibitor will initiate PK and toxicity studies at the Frederick National Laboratory for Cancer Research (FNLCR).

Dr. Bruce Shapiro's anti-tumor RNA nanoparticles project was approved for animal studies to commence in early March at FNLCR. The mouse xenograft studies will obtain data on toxicity, bio-distribution, pathology/histology, and efficacy;

Dr. Don Bottaro's VEGF 3S anti-angiogenesis cancer therapeutic has moved forward with a contract to produce sufficient protein to conduct mouse xenograft efficacy studies.

For a technology to be considered for the IDP, TTC first identifies technologies that could potentially benefit from the program through the Technology Review Group (TRG) in consultation with the Technology Transfer Manager. Then an IDP Panel, comprised of a cross-functional team from TTC and NCI Division of Cancer Treatment and Diagnosis (DCTD), evaluates the technologies and their commercial potential. As part of the evaluation process, the Panel provides verbal feedback to PIs on a development plan, which both parties indicate is extremely useful. Please contact John Hewes, TTC/IDMU, to learn more.

Meeting/Seminar

Resources Available for Writing Technology Abstracts

Ajoy Prabhu, NIH-OTT

At the April TDTC Forum on April 2, 2018, Ajoy Prabhu of OTT Marketing presented a quick primer on writing effective marketing abstracts. The presentation highlighted the reasons for moving away from science-driven abstracts, to a business-friendly format. The main reason he said was so that business development staff at companies (interested in a technology/invention for licensing or collaborating) would find it easier to understand. In addition, Ajoy provided some resources developed by Elaine Ray (Marketing OTT) that are available on the OTT SharePoint site. He encouraged users to bookmark these, and keep them handy as they enter abstracts into TechTracS. The links are as follows:

- Adding New Abstracts to TABS: https://spweb.od.nih.gov/OTT/DTDT/Training/Adding-New-Abstracts-to-TABS.pptx
- Removing Abstracts in TABS: https://spweb.od.nih.gov/OTT/DTDT/Training/Removing-Abstracts-in-TABS.pdf

Finally, Ajoy concluded the talk by offering his group's help in not only writing abstracts, but also doing market research on technologies as well as assistance in finding new licensees. Please contact Ajoy at ajoy.prabhu@nih.gov if you would like to avail of his offer.

New TT Community Staff Member

Jillian Varonin, Ph.D. joined the NCI TTC as a Cancer Research Training Award (CRTA) fellow in January 2018 and is supporting labs in CCR and DCEG. Varonin received her Ph.D. in Biomedical Sciences from the University of California, San Francisco (UCSF); she also spent time as a technology marketing analyst in the UCSF Office of Innovation.

Please forward articles and newsletter suggestions to Jill Roering at roeringj@mail.nih.gov.